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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,159	06/27/2001	Shigeru Kawahara	206269US0PCT	9776

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EXAMINER	
ZUCKER, PAUL A	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 12/28/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,159	KAWAHARA ET AL.	
	Examiner	Art Unit	
	Paul A. Zucker	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-4 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-4 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: As the first line of the specification the following sentence should be inserted:"This application is a 371 of PCT/JP99/06082 filed November 1, 1999 which claims the benefit of JP 310225 and JP 310226 both filed October 30, 1998." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "N-[N-(3,3-dimethylbutyl)-L—aspartyl]-L-phenylalanine methyl ester exhibiting the specific peaks" in lines 2-3. It is unclear from this recitation whether applicant intends that the specific diffraction values are required for the starting material, the product or both. This renders the claim and it's dependant claim indefinite.
3. Claims 1–4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 3 recite the limitation "angles of diffraction (2Θ, Cuκα) of at least 6.0°, 24.8°, 8.2° and 16.5 °" in lines 4-5 and 8-9,

respectively. It is unclear from this recitation whether applicant intends that the qualifier "at least" apply to the peaks values or the peaks themselves. In other words must a peak at 6.0° be present or will a peak at 6.8°.satisfy the limitation of "at least 6.0°". This renders claims 1 and 3 their dependent claims indefinite.

4. Claims 1–4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 3 recite the limitation "(2Θ, Cuκα)" in lines 4 and 8, respectively. The limitation "(2Θ, Cuκα)" renders the claims indefinite because it is unclear whether the limitation(s) enclosed within parentheses are part of the claimed invention. Claims 1 and 3 and their dependent claims are therefore rendered indefinite.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Claude et al (US 5,510,508 04-1996). Claude discloses (Column 4, lines 18-26) a process for the crystallization of N-[N-(3,3-dimethylbutyl)-L—aspartyl]-L-phenylalanine methyl ester (Neotame) from water-methanol solution which contains little or no methanol. Claude is silent with respect to the exact amount of methanol in solution but indicates that methanol is removed by evaporation and thus a low concentration or absence of methanol (cf. instant limitation in claim 2 of "15 wt.% or less" methanol content) can be assumed. Claude further discloses (Column 4, line 19) that crystallization is carried out below 40°C. This is 10°C above the instant temperature of 30°C claimed as a lower limit in claim 1 (line 8). It is therefore reasonable to assume that crystallizations performed at 35 °C, for example, under the conditions described by Claude will have the same diffraction characteristics as those claimed in the instant application. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In the alternative, the invention as a whole is obvious over the disclosure of Claude since it provides no patentable modification of the process as disclosed by Claude: recrystallization of Neotame from a water-methanol solution at a temperature below 40°C. Small adjustments in solvent ratios in the solvent composition disclosed by Claude to achieve the optimum result from the crystallization process would be well within the skill of one of ordinary skill in the art. Thus it would have been obvious for one of ordinary skill in the art to have performed the instant invention at the time applicant asserts it was

made. The motivation would have been to purify Neotame a compound used as an artificial sweetener for human consumption. The expectation for success would have been high since the starting material, solvent composition and product are the same as that disclosed.

Claim Rejections - 35 USC § 103

6. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claude et al (US 5,510,508 04-1996), and further in view of Tosoh et al (WO 93/02101 02-1993). Claude et al (US 5,510,508 04-1996). Claude discloses (Column 4, lines 18-26) a process for the crystallization of Neotame from water-methanol solution which contains little or no methanol. Claude is silent with respect to encouraging the formation of a specific crystalline form of N-[N-(3,3-dimethylbutyl)-L—aspartyl]-L-phenylalanine methyl ester. The use of seeding is standard practice in a crystallization experiment when seed crystals are available. Tosoh teaches (Page 4, lines 5-1) the use of seeding to preferentially form crystals of aspartame having the desired properties. Aspartame is an artificial sweetener very closely related in structure and properties to Neotame. Neotame can, in fact, be synthesized from aspartame in a single step. Tosoh's teaching demonstrates the well understood principle in organic chemistry that a preferred type of crystal can be obtained by seeding with that type of crystal. The invention outlined in claims 3 and 4 simply represents the application of standard laboratory practice to a previously disclosed process for producing crystals of Neotame, presumably having the required crystalline form. The motivation would have been to purify Neotame, a

compound used as an artificial sweetener for human consumption. The expectation for success would have been high since the starting material, solvent composition and product are the same as that disclosed and seeding-a commonly used technique in crystallization experiments -was employed.

Conclusion

7. Claims 1-4 are outstanding. Claims 1-4 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist can be reached on 703-308-1701. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

PAZ
December 21, 2001

GARY GEIST
SUPERVISORY PATENT EXAMINER
TECH CENTER 1600